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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,918	03/24/2004	Stefan Berg	1103326-0527 CON	3973

7470 7590 10/03/2005

WHITE & CASE LLP
PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER	
BERNHARDT, EMILY B	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,918	BERG ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-15,17-19,21,30,31 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-15,17-19,21,30,31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

In view of applicants' response filed 7/18/05 the following still applies.

Claims 18,21,30 and 33 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Reason #1 of the previous action remains. Applicants' traverse is not persuasive. Applicants first stress that the invention is directed to compounds that are selective for the 5-HT1B receptor yet the claims recite all 5-HT mediated disorders. There are currently seven distinct families of 5-HT receptors that have been identified (5-HT1- 5HT7) and many subpopulations have been described and some cloned. Thus there is no reason to doubt that more types/subtypes will be discovered and studied. Applicants mention that "from this knowledge and the instant disclosure, the expectation would be that all of the disorders recited are.... mediated by 5-hydroxytryptamine". There are **no** particular disorders recited in these claims in contrast to claim 19 which is only being rejected under par. one. The examiner has raised several issues why the claims are indefinite which have not been specifically addressed by applicants. It is not believed to be implausible as applicants seem to indicate that the scope of diseases covered could alter over time. This is confirmed by Jones, previously cited who states at p.55, lower right column the following: "In

this short review, we have looked at the disorders that benefit from 5-HT research **currently** and those that may benefit in the **future**."

In such a case how could scope be determined with certainty when it may turn out that all diseases may be affected by the mediation of one or more 5HT receptors in whole or in part. If a disease responds to a second drug but not a first, both of whom activate a 5HT receptors *in vitro*, can one really conclude that the disease falls within the claims? It may be the positive response to the second drug is the result of some other biological mechanism which the second drug possesses but not the first. It is quite common for drugs to work by many mechanisms. Thus how many drugs need to be tested before it can be concluded if a disease is mediated or not by this biological process ? The same can be said for the scope of mammalian hosts. One may observe a positive response employing an instant compound for a particular disease in one host but not another. It is quite common for pharmaceuticals to work only with some people, not all, much less any and all mammalian species. With regard to knowing who is in need vs who is not, how can such be determined? One may have no visible symptoms and still be in need. It may turn out with further research that everyone is in need or that one only needs a specific type or subtype of serotonin receptor among the many types and subtypes that exist. For all of the above reasons, determining the actual scope of such a

claim will involve not only extensive but also potentially inconclusive research which renders the claim(s) rejected herein indefinite. It is not agreed that it is irrelevant to patentability whether the disorders are not presently known as applicants state since as stated previously- the test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined **their** invention and not what may be discovered by **future** research.

The examiner in this case is not privy to the prosecution conducted in an earlier patent nor bound by the reason(s) which ultimately determined patentability. Note In re Giolito 188 USPQ 645. See also, Minnesota Mining & Manufacturing Company 62 USPQ 119.

Reason #2 of the previous action is withdrawn in view of the additional requirement in 21 that the disorder must pertain to the central nervous system.

Claims 1,2,4-15,17-19,21,30,31and 33 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Both reasons of the previous action remain. With regard to solvates, applicants' statement that hydrates are "preferred" does not avoid the rejection since the fact is water is the only

solvent described as suitable. It is evident that the instant compounds and synthetic precursors do not readily form solvates given the many solvents employed in the working examples which do not result in solvates. As was stated in Morton International Inc v. Cardinal Chemical Co. 28 USPQ2d 1190 at p.1194 : "The specification purports to teach with over fifty examples, the preparation of the claimed compounds with the required connectivity. However... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds..there is... no evidence that such compounds even exist." . The same applies in the present case.

With regard to reason #2 describing one compound in an assay test is not synonymous with providing an enabling disclosure that is commensurate in scope for all the claimed uses and is reasonably predictive of **in vivo** efficacy. The references previously addressed do not support such a range of uses which includes entire classes of disorders nor do the references cited in applicants' most recent response. Halazy admits that the uses besides depression are at best speculative pending the outcome of future research and Gothert is even less persuasive as the majority of the article deals at best with testing in animal models for depression and for implicating CNS disorders based on serotonin-type with no clear correlation of preclinical or clinical effectiveness for compounds that are selective

towards the 5-HT1B receptor. Note Genentech vs. Novo Nordisk 42 USPQ 2d 1001 especially left column at p.1005 which states the following:"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may be workable." . In the same decision at p.1004 it is clearly stated that "to be enabling the specification must teach ... how to make and use the full scope of the claimed invention without undue experimentation."

Applicants are requested to supply the needed information regarding the Gothert article for consideration by the examiner. See p. 6 of the previous response.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

E Bernhardt

Emily Bernhardt
Primary Examiner
Art Unit 1624